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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,567	09/04/2003	Futoshi Okada	Furuya Case 1407	6434
23474	7590	05/26/2004	EXAMINER	
FLYNN THIEL BOUTELL & TANIS, P.C. 2026 RAMBLING ROAD KALAMAZOO, MI 49008-1699			KOSSON, ROSANNE	
			ART UNIT	PAPER NUMBER

1651

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/655,567

Applicant(s)

OKADA ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a tumor with melon superoxide dismutase (SOD), does not reasonably provide enablement for a method of treating a tumor with any SOD.

Further, Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating melon SOD with gliadin, does not reasonably provide enablement for treating any SOD with any agent or with any protein or any lipid. Nor is the specification enabling for treating any SOD with gliadin.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Specifically, because only one SOD is disclosed, and because only one agent for treating this SOD is disclosed, Applicants have provided no guidance for treating or preventing tumors with any other SODs or for treating SOD with any other agents for use in tumor therapy. Given the complete lack of guidance in this regard, the skilled artisan would not be able to determine without a degree of experimentation which would

be considered undue, how to search for or prepare compounds other than the one disclosed for tumor treatment. A holding of non-enablement is clearly required.

Additionally, claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a tumor with melon SOD combined with gliadin, does not reasonably provide enablement for a method of preventing a tumor by the administration of treated SOD, protein or lipid-treated SOD, SOD combined with gliadin, or melon SOD combined with gliadin. The specification discloses administering SOD combined with gliadin to mice with tumors, to a human with colon cancer, and to a human who had had a cancerous prostate removed. Shrinkage of the tumors was measured, and the subjects were examined for reappearance of tumors. Thus, Applicants have not demonstrated administration of an SOD formulation to prevent tumors. Prevention of tumors in a subject may be asserted in any case where an SOD formulation is administered to a normal subject, and the subject has not yet developed tumors (or prostate or colon cancer). Any animal that has consumed a food (such as a melon) or composition comprising SOD and that has not developed tumors would create an example that reads on claim 1. If the food or composition comprises another protein or a lipid, as does melon, that example would also read on claim 2. Therefore, a holding of non-enablement is clearly required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 2 are vague and indefinite for reciting "treated" SOD. The procedure and nature of treating the SOD are not defined in the specification, and the metes and bounds of the claims are therefore indefinite. Clarification is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Ginoux et al. (U.S. 5,616,323). Ginoux discloses a protein extract from melon (*Cucumis melo*) containing superoxide dismutase that may be used to treat cancer (see column 1, lines 7-10 and 59-65, and column 2, lines 21-24). Because the superoxide dismutase is contained in a crude extract, it is mixed with the other proteins and lipids found in melon pulp (see column 5, lines 21-29). The superoxide dismutase is, therefore a treated superoxide dismutase, as well as a superoxide dismutase treated with a protein or lipid (see "treated" in specification, p. 4, 3d and 4<sup>th</sup> new paragraphs.) A holding of anticipation over the cited claims is therefore required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murcia et al. (J Food Prot 64(12):2037-2046, 2001) in view of Postaire et al. (U.S. 6,045,809) and Ginoux (U.S. 5,616,323). Murcia discloses that melon has significant SOD activity, as shown by its antioxidant and free radical (OH<sup>·</sup>) scavenging activity (see pp. 2039-2043, Results and Discussion and Tables 1-3). Postaire discloses a composition comprising superoxide dismutase (SOD) and gliadin, which stabilizes this enzyme at acidic pH and provides a controlled release formulation (see column 3, lines 1-11). It would be obvious to one of ordinary skill in the art to formulate the SOD-containing composition of Murcia (melon pulp) as the gliadin film-coated SOD-

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containing composition of Postaire because the formulation of Postaire is adapted for oral administration, good bioavailability and therapeutic efficacy (see column 1, lines 6-9). Further, the skilled artisan would be motivated to use the SOD-containing composition of Murcia because melons are a readily available source possessing potent SOD activity. Ginoux discloses administering SOD-containing extracts from melon to treat cancer (see column 1, lines 6-10 and 59-65, column 2, lines 21-24, and column 5, lines 13-29). Thus, it would be obvious to one of ordinary skill in the art to use a gliadin-coated SOD-containing composition to treat cancer, rather than uncoated SOD-containing melon pulp, because, as recited in Postaire, the gliadin-coated composition is more acid-stable and longer acting. As asserted in Ginoux, the gliadin-coated SOD-containing composition would be especially useful in the treatment of cancers. A holding of obviousness is therefore required.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Rosanne Kosson  
Examiner  
Art Unit 1651

rk  
2004-05-13

  
FRANCISCO PRATS  
PRIMARY EXAMINER